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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
10/600,175	06/20/2003	Robert I. Rudko	LE-204J	9703	
7590 03/09/2006			EXAMINER		
Iandiorio & Teska 260 Bear Hill Road			FARAH, AHMED M		
Waltham, MA 02451-1018			ART UNIT	PAPER NUMBER	
			3735		
			DATE MAILED: 03/09/2006		

Please find below and/or attached an Office communication concerning this application or proceeding.

		<u> </u>				
	Application No.	Applicant(s)	1			
	10/600,175	RUDKO ET AL.				
Office Action Summary	Examiner	Art Unit	1			
	Ahmed M. Farah	3735	_			
The MAILING DATE of this communication ap Period for Reply	ppears on the cover sheet with t	the correspondence address				
A SHORTENED STATUTORY PERIOD FOR REPL WHICHEVER IS LONGER, FROM THE MAILING I Extensions of time may be available under the provisions of 37 CFR 1 after SIX (6) MONTHS from the mailing date of this communication.  If NO period for reply is specified above, the maximum statutory period Failure to reply within the set or extended period for reply will, by statu Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	DATE OF THIS COMMUNICA .136(a). In no event, however, may a reply d will apply and will expire SIX (6) MONTHS te, cause the application to become ABANI	FION. be timely filed from the mailing date of this communication. FONED (35 U.S.C. § 133).				
Status						
1) Responsive to communication(s) filed on	·					
,	This action is <b>FINAL</b> . 2b)⊠ This action is non-final.					
,						
closed in accordance with the practice under	Ex parte Quayle, 1935 C.D. 1	1, 453 O.G. 213.				
Disposition of Claims						
4) Claim(s) 1-23 is/are pending in the application	n.					
4a) Of the above claim(s) is/are withdra	awn from consideration.					
5) Claim(s) is/are allowed.						
6)⊠ Claim(s) <u>1-23</u> is/are rejected.						
7) Claim(s) is/are objected to.	or election requirement		i			
8) Claim(s) are subject to restriction and/	or election requirement.					
Application Papers						
9)☐ The specification is objected to by the Examin						
10)☐ The drawing(s) filed on is/are: a)☐ ac						
Applicant may not request that any objection to the						
Replacement drawing sheet(s) including the corre						
Priority under 35 U.S.C. § 119	•					
12) Acknowledgment is made of a claim for foreig a) All b) Some * c) None of:	n priority under 35 U.S.C. § 1	19(a)-(d) or (f).				
1. Certified copies of the priority documents have been received.						
2. Certified copies of the priority documer						
3. Copies of the certified copies of the pri		ceived in this National Stage				
application from the International Bure  * See the attached detailed Office action for a lis		ceived.				
Gee the attached detailed Office action for a no	cor are continued depice from					
Attachment(s)	_					
1) Notice of References Cited (PTO-892)	4) Interview Sum Paper No(s)/N	mary (PTO-413) fail Date				
<ul> <li>2) Notice of Draftsperson's Patent Drawing Review (PTO-948)</li> <li>3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/0 Paper No(s)/Mail Date 1/26/05;1/9/06.</li> </ul>	a. 🗖	mal Patent Application (PTO-152)				

Application/Control Number: 10/600,175

Art Unit: 3735

#### **DETAILED ACTION**

### **Double Patenting**

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-23 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-26 of copending Application No. 10/753,693. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are directed to analogous apparatus and method of use for endovascular tissue removal.

This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Application/Control Number: 10/600,175

Art Unit: 3735

## Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 22 is rejected under 35 U.S.C. 102(b) as being anticipated by Stevens US Patent No. 5,545,214.

Stevens discloses apparatus and method for replacement of heart valve, comprising the steps of: introducing a lumen within the vasculature of a patient proximate a heart valve to be resected; introducing ablative mechanical energy into the lumen; and rotating the lumen to resect the heart valve.

## Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-21 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stevens US Patent No. 5,370,685 in view of Rudko et al. US Patent No. 5,830,210.

Stevens discloses an endovascular tissue removal device as claimed except the use of optical energy and delivery optical fibers to provide the tissue removal/treatment energy as presently claimed. Rudko et al. disclose an alternative endovascular tissue

Art Unit: 3735

removal device in which plurality of optical fibers disposed on an expandable member deliver ablative laser energy to a desired tissue location. Therefore, at the time of the applicant's invention, it would have been obvious to one skilled in the art to use optical energy and a delivery system as an equivalent alternative means to the mechanical energy of Stevens in order to remove a desired vascular tissue.

#### Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ahmed M. Farah whose telephone number is (571) 272-4765. The examiner can normally be reached on Mon-Thur 9:30 AM-7: 30 PM, and 9:30 AM - 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on (571) 272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

March 4, 2006.



Page 4